



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Mar Tomo et al.

Serial No.: 08/726,211

Filed: October 4, 1996

For: INHIBITION OF BCL-2 PROTEIN
EXPRESSION BY LIPOSOMAL
ANTISENSE
OLIGODEOXYNUCLEOTIDES

Group Art Unit: 1636

Examiner: Daniel M. Sullivan

Atty. Dkt. No.: UTXC:504

08/17/2004 LWONDIM1 00000018 08726211

01 FC:1806

180.00 OP

**CERTIFICATE OF MAILING
37 C.F.R. 1.8**

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail in an envelope addressed to: MS AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date below:

August 11, 2004

Date

David L. Parker

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

MS AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:


In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Supplemental Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner.

In accordance with 37 C.F.R §§ 1.97(g), (h), this Supplemental Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be

construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

A fee as set forth in 37 C.F.R. § 1.17(p) in the amount of \$180.00 is enclosed herewith. If an appropriate check has not been enclosed, or if it is insufficient, the Commissioner is authorized to deduct the appropriate fee from Fulbright & Jaworski Account No.: 50-1212/UTXC:504.

Applicants respectfully request that the listed documents be made of record in the present case.

Respectfully submitted,


David L. Parker
Reg. No. 32,165
Attorney for Applicants

FULBRIGHT & JAWORSKI L.L.P.
600 Congress Avenue, Suite 2400
Austin, Texas 78701
(512) 474-5201

Date: August 11, 2004



Form PTO-1449 (modified)

List of Patents and Publications for Applicant's

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Atty. Docket No.

UTXC:504

Serial No.

08/726,211

Applicant

Mar Tomo *et al.*

Filing Date:

October 4, 1996

Group:

1636

U.S. Patent Documents

See Page 1

Foreign Patent Documents

See Page 1

Other Art

See Page 1

U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
	A72	5,641,662	6/24/97	Debs and Zhu	435	172.1	3/10/93
	A73	5,837,838	11/17/98	Reed and Xu	536	23.1	3/14/97
	A74	5,981,501	11/09/99	Wheeler <i>et al.</i>	514	44	6/07/95
	A75	5,989,912	11/23/99	Arrow <i>et al.</i>	435	375	12/15/98
	A76	6,030,954	2/29/00	Wu and Wu	514	44	6/02/95
	A77	6,042,846	3/28/00	Lopez-Berestein and Tari	424	450	7/09/98

Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
	B21	WO 97/07784 ✓	3/06/97	PCT			English
	B22	WO 98/14172 ✓	4/09/98	PCT			English
	B23	WO 98/56905 ✓	12/17/98	PCT			English

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

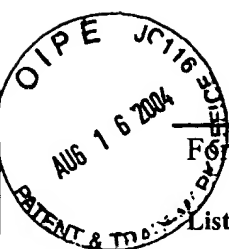
Exam. Init.	Ref. Des.	Citation
	C141	Agrawal, "Antisense oligonucleotides: towards clinical trials," TIB Tech, 14(10):376-387, 1996.
	C142	Agrawal et al., "Antisense therapeutics: is it as simple as complementary base recognition," Molecular Medicine Today, 6:72-81, 2000.
	C143	Aisenberg, "Coherent view of non-Hodgkin's lymphoma," J. Clin. Oncol., 13(10):2656-2675, 1995.
	C144	Baichwal and Sugden, "Vectors for gene transfer derived from animal DNA viruses: Transient and stable expression of transferred genes," In: Kucherlapati R, (ed.) Gene transfer. New York: Plenum Press, pp. 117-148, 1986.

25442099.1

EXAMINER:

DATE CONSIDERED:

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.



Form PTO-1449 (modified)

Atty. Docket No.

UTXC:504

Serial No.

08/726,211

List of Patents and Publications for Applicant's

Applicant

Mar Tomo *et al.*

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Filing Date:

October 4, 1996

Group:

1636

U.S. Patent Documents

See Page 1

Foreign Patent Documents

See Page 1

Other Art

See Page 1

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C145	Bangham <i>et al.</i> , "Diffusion of univalent ions across the lamellae of swollen phospholipids," <i>J. Mol. Biol.</i> , 13:238-252, 1965.
	C146	Benvenisty and Reshif, "Direction introduction of genes into rats and expression of the genes," <i>Proc. Nat'l Acad. Sci. USA</i> , 83:9551-9555, 1986.
	C147	Chang <i>et al.</i> , "Foreign gene delivery and expression in hepatocytes using a hepatitis B virus vector," ABSTRACT, <i>Hepatology</i> , 14(4):124A, 1991.
	C148	Chen and Okayama, "High-efficiency transfection of mammalian cells by plasmid DNA," <i>Mol. Cell Biol.</i> , 7(8):2745-2752, 1987.
	C149	Chirila <i>et al.</i> , "The use of synthetic polymers for delivery of therapeutic antisense oligodeoxynucleotides," <i>Biomaterials</i> , 23:321-342, 2002.
	C150	Coffin, "Retroviridae: the viruses and their replication," <i>In: Virology</i> , Fields <i>et al.</i> (eds.), New York: Raven Press, pp. 1767-1847, 1996.
	C151	Cotter <i>et al.</i> , "Human Bcl-2 antisense therapy for lymphomas," <i>Biochimica et Biophysica Acta</i> , 1489:97-106, 1999.
	C152	Coupar <i>et al.</i> , "A general method for the construction of recombinant vaccinia virus expressing multiple foreign genes," <i>Gene</i> , 68:1-10, 1988.
	C153 ✓	Crooke, "Antisense research and application," Springer, NY, 1-50, 1998.
	C154	Crystal, <i>Science</i> , 270:404-410, 1995.
	C155	Deamer and Uster, "Liposome Preparation: Methods and Mechanisms," <i>LIPOSOMES</i> , M. Ostro ed. (1983).
	C156	Dubensky <i>et al.</i> , "Direct transfection of viral and plasmid DNA into the liver or spleen of mice," <i>Proc. Nat'l Acad. Sci. USA</i> , 81:7529-7533, 1984.
	C157	Fecheimer <i>et al.</i> , "Transfection of mammalian cells with plasmid DNA by scrape loading and sonication loading," <i>Proc. Nat'l Acad. Sci. USA</i> , 84(23):8463-8467, 1987.
	C158	Fraley <i>et al.</i> , "Entrapment of a bacterial plasmid in phospholipid vesicles: potential for gene transfer," <i>Proc. Nat'l Acad. Sci. USA</i> , 76(7):3348-3352, 1979.
	C159	Friedman <i>et al.</i> , "CCAAT/enhancer-binding protein activates the promoter of the serum albumin gene in cultured hepatoma cells," <i>Genes & Devel.</i> 3:1314-1322, 1989.

25442099.1

EXAMINER:

DATE CONSIDERED:

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.



Form PTO-1449 (modified)

Atty. Docket No.

UTXC:504

Serial No.

08/726,211

List of Patents and Publications for Applicant's

Applicant

Mar Tomo *et al.*

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Filing Date:

October 4, 1996

Group:

1636

U.S. Patent Documents

See Page 1

Foreign Patent Documents

See Page 1

Other Art

See Page 1

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

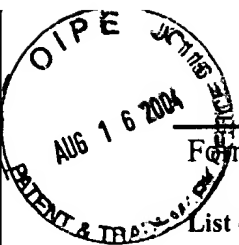
Exam. Init.	Ref. Des.	Citation
	C160	Ghosh and Bachhawat, "Targeting of liposomes to hepatocytes," <i>In</i> : Wu G. Wu C ed., Liver diseases, targeted diagnosis and therapy using specific receptors and ligands, New York: Marel Dekker, pp. 87-103, 1991.
	C161	Gleave <i>et al.</i> , "Targeting bcl-2 gene to delay androgen-independent progression and enhance chemosensitivity in prostate cancer using antisense bcl-2 oligodeoxynucleotides," <i>Urology</i> , 54(Suppl 6A):36-46, 1999.
	C162	Gopal, "Gene transfer method for transient gene expression, stable transformation, and cotransformation of suspension cell cultures," <i>Mol. Cell Biol.</i> , 5:1188-1190, 1985.
	C163	Graham and van der Eb, "A new technique for the assay of infectivity of human adenovirus 5 DNA," <i>Virology</i> , 52:456-467, 1973.
	C164	Graham <i>et al.</i> , "Characteristics of a human cell line transformed by DNA from human adenovirus type 5," <i>J. Gen. Virol.</i> , 36:59-72, 1977.
	C165	Harland and Weintraub, "Translation of mammalian mRNA injected into <i>Xenopus oocytes</i> is specifically inhibited by antisense RNA," <i>J. Cell Biol.</i> , 101:1094-1099, 1985.
	C166	Hermionat and Muzycska, "Use of adeno-associated virus as a mammalian DNA cloning vector: Transduction of neomycin resistance into mammalian tissue culture cells," <i>Proc. Nat'l Acad. Sci. USA</i> , 81:6466-6470, 1984.
	C167	Horwich <i>et al.</i> , "Synthesis of hepadnavirus particles that contain replication-defective duck hepatitis B virus genomes in cultured HuH7 cells," <i>J. Virol.</i> 64(2):642-650, 1990.
	C168	Jansen <i>et al.</i> , "bcl-2 antisense therapy chemosensitizes human melanoma in SCID mice," <i>Nature Medicine</i> , 4(2):232-234, 1998.
	C169	James, "Towards gene-inhibition therapy: a review of progress and prospects in the field of antiviral antisense nucleic acids and ribozymes," <i>Antiviral Chemistry and Chemotherapy</i> , 2(4):191-215, 1991.
	C170	Johnson <i>et al.</i> , "Patterns of survival in patients with recurrent follicular lymphoma: a 20-year study from a single center," <i>J. Clin. Oncol.</i> , 13(1):140-147, 1995.
	C171	Klein <i>et al.</i> , "High-velocity microprojectiles for delivering nucleic acids into living cells," <i>Nature</i> , 327:70-73, 1987.

25442099.1

EXAMINER:

DATE CONSIDERED:

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.



Form PTO-1449 (modified)		Atty. Docket No. UTXC:504	Serial No. 08/726,211
List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		Applicant Mar Tomo <i>et al.</i>	
		Filing Date: October 4, 1996	Group: 1636
U.S. Patent Documents <i>See Page 1</i>	Foreign Patent Documents <i>See Page 1</i>	Other Art <i>See Page 1</i>	

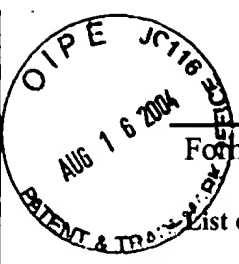
Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C172	Konopleva <i>et al.</i> , "Inhibition of Bcl-2 with liposomal P-ethoxy antisense oligonucleotides induces apoptosis in the presence of high level of Bcl-XL and is critically depending on baseline Bcl-2 levels in AML," <i>J. Amer. Soc. Hamatology</i> , 92(10)Suppl. 1, Part 1 of 2, Abstract No. 2100, 1998.
	C173	Mann <i>et al.</i> , "Construction of a retrovirus packaging mutant and its uses to produce helper-free defective retrovirus," <i>Cell</i> , 33:153-159, 1983.
	C174	McDonnell and Korsmeyer, "Progression from lymphoid hyperplasia to high-grade malignant lymphoma in mice transgenic for the t(14;18)," <i>Nature</i> , 349:254-256, 1991.
	C175	Milner <i>et al.</i> , "Selecting effective antisense reagents on combinatorial oligonucleotide arrays," <i>Nature</i> , 15:537-541, 1997.
	C176	Miyake <i>et al.</i> , "Antisense Bcl-2 oligodeoxynucleotides inhibit progression to androgen-independence after castration in the Shionogi tumor model," <i>Cancer Res.</i> , 59:4030-4034, 1999.
	C177	Neilan <i>et al.</i> , "An African Swine fever virus with similarity to the protooncogene <i>bcl-2</i> and the Epstein-Barr virus gene <i>BHRF1</i> ," <i>J. Virol.</i> , 67(7):4391-4394, 1993.
	C178	Nicolas and Rubenstein, "Retroviral vectors," <i>In: Vectors: A survey of molecular cloning vectors and their uses</i> , Rodriguez and Denhardt, (eds.), Stoneham: Butterworth, pp. 494-513, 1988.
	C179	Paskind <i>et al.</i> , "Dependence of moloney murine leukemia virus production on cell growth," <i>Virology</i> , 67:242-248, 1975.
	C180	Palu <i>et al.</i> , "In pursuit of new developments for gene therapy of human diseases," <i>Biotech.</i> , 68:1-13, 1999.
	C181	Pearson <i>et al.</i> , "Identification of an Epstein-Barr virus early gene encoding a second component of the restricted early antigen complex," <i>Virology</i> , 160:151-161, 1987.
	C182	Pihl-Carey, "Disease drug fails in phase III," <i>BioWorld Today</i> , 10:1-2, 1999.
	C183	Potter <i>et al.</i> , "Enhancer-dependent expression of human κ immunoglobulin genes introduced into mouse pre-B lymphocytes by electroporation," <i>Proc. Nat'l Acad. Sci. USA</i> , 81:7161-7165, 1984.
	C184	Ridgeway, "Mammalian expression vectors," <i>In: Rodriguez RL, Denhardt DT, (ed.) Vectors: A survey of molecular cloning vectors and their uses</i> . Stoneham: Butterworth, pp. 467-492, 1988.
	C185	Rippe <i>et al.</i> , "DNA-mediated gene transfer into adult rat hepatocytes in primary culture," <i>Mol. Cell Biol.</i> , 10(2):689-695, 1990.

25442099.1

EXAMINER:**DATE CONSIDERED:**

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.



Form PTO-1449 (modified)

Atty. Docket No.
UTXC:504Serial No.
08/726,211

List of Patents and Publications for Applicant's

Applicant
Mar Tomo *et al.*

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Filing Date:
October 4, 1996Group:
1636U.S. Patent Documents
*See Page 1*Foreign Patent Documents
*See Page 1*Other Art
See Page 1

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C186	Stratford-Perricaudet and Perricaudet, "Gene transfer into animals: the promise of adenovirus," pp. 51-61, <i>In: Human Gene Transfer</i> , Eds. O. Cohen-Haguenauer and M. Boiron Editions John Libbey Exrotext, France, 1991.
	C187	Szoka and Papahadjopoulos, "Procedude for preparation of liposimes with large internal aqueous space and high capture by reverse-phase evaporation," <i>Proc. Nat'l Acad. Sci. U.S.A.</i> 75(9):4194-4198, 1978.
	C188	Temin, "Retrovirus vectors for gene transfer: Efficient integration into and expression of exogenous DNA in vertebrate cell genome," <i>In: Gene Transfer</i> , Kucherlapati (ed.), New York: Plenum Press, pp. 149-188, 1986.
	C189	Tur-Kaspa <i>et al.</i> , "Use of electroporation to introduce biologically active foreign genes into primary rat hepatocytes," <i>Mol. Cell Biol.</i> , 6(2):716-718, 1986.
	C190	Verma <i>et al.</i> , <i>Nature</i> , 389:238-243, 1997.
	C191	Wagner <i>et al.</i> , "Antisense gene inhibition by pligonucleotides containing C5 propyne pyrimidines," <i>Science</i> , 260:1510-1513, 1993.
	C192	Wu and Wu, "Evidence for targeted gene delivery to Hep G2 hepatoma cells in vitro," <i>Biochemistry</i> , 27:887-892, 1988.
	C193	Wu and Wu, "Receptor-mediated <i>in vitro</i> gene transformations by a soluble DNA carrier system," <i>J. Biol. Chem.</i> , 262(10):4429-4432, 1987.
	C194	Yang <i>et al.</i> , "In vivo and in vitro gene transfer to mammalian somatic cells by particle bombardment," <i>Proc. Nat'l Acad. Sci. USA</i> , 87:9568-9572, 1990.
	C195	Zelenin <i>et al.</i> , "High-velocity mechanical DNA transfer of the chloramphenicolacetyl transferase gene into rodent liver, kidney and mammary gland cells in organ explants and in vivo," <i>FEBS Lett.</i> , 280(1):94-96, 1991.
	C196	Ziegler <i>et al.</i> , "Induction of apoptosis in small-cell lung cancer cells by an antisense oligodeoxynucleotide targeting the Bcl-2 coding sequence," <i>J. Nat'l Cancer Institute</i> , 89(14):1027-1036, 1997.

25442099.1

EXAMINER:

DATE CONSIDERED:

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.